

Serial No.: 10/026,819
Atty. Docket No.: P67397US0

REMARKS

The Office Action mailed November 4, 2004, has been carefully reviewed and by this Amendment, Applicants have canceled claim 28, and amended claims 1-4, 7, 16, 17, 20-23, 26, 27, 29, 31-34, 41, 60, 62-64 and 67-72. Claims 1-27 and 29-79 are pending in the application. Claims 1, 60 and 74 are independent. Claims 5, 6, 8-15, 18, 19, 24, 25, 28, 30, 35-40, 42-59, 61, 65, 66 and 73-79 are withdrawn from further consideration.

As an initial matter, Applicants have identified the pending and withdrawn status of the claims according to their election of species made in the Response to Restriction Requirement filed August 9, 2004. The Examiner's listing of withdrawn claims includes some claims that read on the elected species. In addition, the Examiner's withdrawn listing does not include some claims that belong to non-elected species, e.g., claims 73-75. Therefore, Applicants have reviewed the claims and present claims 1-4, 7, 16, 17, 20-23, 26, 27, 29, 31-34, 41, 60, 62-64 and 67-72 as being those claims that read on the elected species of Figure 1 and that are therefore under consideration in accordance with the Examiner's search of the elected species.

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The Examiner objected to claims 3 and 16 as containing informalities which Applicants have corrected herein.

The Examiner rejected claims 1, 3, 4, 7, 16, 21-23, 26, 28, 29, 32-34, 60, 62-64, 67 and 70-72 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,602,244 to Kavanagh et al. ("Kavanagh"), rejected claims 1, 41 and 60 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,850,350 to Jackson, and rejected claims 27 and 68 under 35 U.S.C. 103(a) as being unpatentable over Kavanagh in view of U.S. Publication No. 2004/0158231 to Tanghoj et al. or in view of U.S. Publication No. 2004/0153051 to Israelsson et al.

As set forth in amended claims 1 and 60, the present invention is directed to a catheter assembly that allows for non-contaminated insertion of the catheter into a urinary canal. The assembly includes a urinary catheter having a proximal end adapted for insertion into a urinary canal and an opposite distal end, and a catheter package having a hose with a cavity for accommodation of the catheter. The proximal end of the package has a catheter outlet adapted to dismantle or dispense the proximal end of the catheter from the catheter package. The package is also provided with an opening, separate from the catheter outlet, for draining a liquid substance out of the

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package. This opening is closed by a *closing structure that is connected to the catheter for causing the package to be opened upon removal of the catheter from the package*. This is not shown or suggested by the prior art.

Kavanagh discloses a device with a catheter 15 located in a flexible container 11. The insertable end of the catheter (which Kavanagh calls the "distal" end but which corresponds with the "proximal" end as defined by the present invention) passes through a catheter gripping and lubricating device 16, which may be said to dismantle or dispense the insertable end from the container 11. At the opposite end of the catheter, i.e., that end that remains within the container 11, the catheter is provided with a frusto-conical fitting 18 which prevents or restrains extraction of the catheter from the container, the fitting being unable to pass through the narrow opening defined by the gripping and lubricating device 16. There is, in Kavanagh, no opening in the container *separate from the catheter outlet* and no structure *connected to the catheter* that, upon removal of the catheter from the container, serves to open the *separate opening in the container* and thereby open the distal end of the container for draining of the package, as claimed by the present invention.

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Jackson discloses a closed system for tracheal suction and ventilation. The system includes a suction catheter 4, and a suction control valve 6 which is attached to the distal end of the catheter (as "distal" is defined by the present invention). Upon removal from a sterile package (not shown), a breathing tube (also not shown) from the ventilation equipment is attached to the male connector 70. As taken from the package, the suction control valve has already been attached to the catheter 4. The tapered end 56 thereof is inserted into a suction connection tube (not shown). The endo tube adaptor 110 is attached to the female end 26 of the connector unit 10. To open the passage for the catheter, the flange 76 is rotated to move the hole 46 in alignment with lumen 48. The catheter is then moved through the unit 10 a few inches at a time, while being grasped through the sleeve 12 (see column 6, line 64, to column 7, line 10). In other words, closure of the passage is effected merely by the hole 46 being out of alignment with the lumen 48 and, to open the passage, the flange 76 is rotated; there is no connection between this manner of closing a passage and the closing structure connected to a urinary catheter as claimed by the present invention, which structure, upon removal of the catheter from the

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package, opens the package for draining of urine from the package.

Claims 1 and 60 are therefore not anticipated by either Kavanagh or Jackson, nor are they suggested thereby. Jackson teaches only a catheter in fixed connection with the suction control valve in an entirely different field of use. Having a catheter package with an opening separate from the catheter outlet that serves to ensure free passage of urine out of the distal end of the package is not contemplated by Jackson as this patent is not even remotely concerned with urine drainage.

Kavanagh mentions that the pouch or package 11 could be used as a fluid collection chamber (see column 6, lines 6-8). However, in that case the package should definitely not be opened upon removal of the catheter therefrom. Hence, there is no suggestion in Kavanagh of a closing structure connected to the catheter for opening the package in the manner claimed by the present invention and, in fact, Kavanagh is not at all concerned about problems related to opening of the package.

For at least the foregoing reasons, claims 1 and 60 as amended are patentable over the prior art. Favorable reconsideration and allowance thereof is requested. Claims 2-4, 7, 16, 17, 20-23, 26, 27, 29, 31-34, 41, 62-64 and 67-72 are also

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in condition for allowance as claims properly dependent on an allowable base claim and for the subject matter contained therein.

The Examiner provisionally rejected claims 1, 3, 4, 7, 16, 21-23, 26-29, 32-34, 60, 62-64, 67 and 70-72 under 35 U.S.C. 101 as claiming the same invention as that of claims 1-20 of co-pending patent application, Serial No. 10/482,229, and as that of claims 1-87 of co-pending patent application, Serial No. 10/183,984, both co-pending applications being to Tanghoj et al. ("the Tanghoj applications"). In that the rejection is provisional, the conflicting claims in the Tanghoj applications not having been patented, Applicants defer response to this rejection pending possible further amendment and the determination of the final claims in the Tanghoj applications, as well as the identification of allowable subject matter in this application under 35 U.S.C. 102 and 35 U.S.C. 103.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance.

A further Information Disclosure Statement, with the requisite fee, is being filed concurrently herewith.

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Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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